

# **Patient-Delivered Therapy of Antibiotics for *Chlamydia trachomatis***

## **Guidance For Medical Providers In California**

California Department of Health Services STD Control Branch  
June 4, 2001

### **Introduction**

As of January 1, 2001, California medical providers have a new option for ensuring effective partner treatment for the sexual partners of patients diagnosed with chlamydia. This document is intended to provide guidance for clinical practice in the implementation of this new California legislation allowing medical providers to prescribe or dispense antibiotic therapy for the sex partners of patients infected with genital chlamydia infection (Health and Safety Code Section 120582).

### **Executive Summary**

SB 648 (Ortiz, Chapter 835) amended current law and allows physicians to prescribe and nurse-practitioners, physician assistants and certified nurse-midwives to dispense antibiotic therapy for the male and female sexual partners of male and female individuals infected with genital *Chlamydia trachomatis*, even if they have not been able to perform an exam of the patient's partner(s).

The following guidelines provide information on the most appropriate patients, medication and counseling procedures recommended to maximize patient and public health benefit while minimizing risk.

- First-choice strategy: Attempt to bring partners in for evaluation and treatment
- Most appropriate patients: Females with male partners
- Diagnosis: Laboratory-confirmed genital chlamydia infection without co-infection with gonorrhea or other complications
- Most appropriate partners: Males who are uninsured or unlikely to seek medical services
- Medication: The law does not specify, but recommended prescription is for Azithromycin (Zithromax\*) 1 gram (250 mg tablets x 4) orally once
- Number of doses are limited to the number of known sex partners in past 60 days
- Education materials must accompany medication
- Patient counseling: Abstinence until 7 days after treatment and until 7 days after partners have been treated
- Evaluation: Recommend re-test patients for chlamydia three to four months after treatment
- Adverse reactions: Does not protect provider from liability, as is the case for any medical treatment. Report to 1-866-556-3730 (toll-free)

**Additional Resources:**

For information on local chlamydia efforts, please visit the California Chlamydia Action Coalition's website at [www.ucsf.edu/castd](http://www.ucsf.edu/castd), call your local STD control program, or call the California Department of Health Services' STD Control Branch at (510) 540-2657.

The California STD/HIV Prevention Training offers courses on partner management, notification and counseling. Please visit the website at [www.stdhivtraining.org](http://www.stdhivtraining.org) or call (510) 883-6600.

**Background**

Genital chlamydia infection is a significant public health problem. More than 90,000 cases of chlamydia were reported in California in 2000 making it the most common reportable disease. However, because the majority of infections are asymptomatic and undiagnosed, and because of underreporting, it is estimated that as many as 600,000 Californians become infected each year. Adolescent females have the highest risk of infection. In fact, an estimated 5 to 10% of sexually active adolescent females are currently infected(1).

Chlamydia is a leading cause of pelvic inflammatory disease, chronic pelvic pain, ectopic pregnancy and preventable infertility in women. Patients with chlamydia are also at increased risk of acquiring sexually transmitted HIV. **The risk of adverse reproductive health complications of chlamydia infection increases significantly with repeat infections, which occur in 15-30% of young women within six months.**

To prevent repeat infections, partners must be provided timely and appropriate antibiotic treatment. However, because infected partners, and indeed most patients, are generally asymptomatic, they are unlikely to seek medical treatment. Even when providers counsel patients about the need for partner treatment, some partners have limited or no access to medical care or choose not to seek care.

This new law (Section 120582 of the Health and Safety Code) provides an exception to the Medical Practice Act, which states that the prescribing, dispensing, or furnishing of dangerous drugs, as defined, without a good faith prior examination and medical indication constitutes unprofessional conduct. The new law provides that a licensee acting in accordance with provisions of the law with regard to a prescription for antibiotic therapy has not committed unprofessional conduct under this provision.

**Rationale**

Evidence suggests that repeat chlamydia infections place women at a significantly increased risk of developing upper genital tract complications, and infertility. The single most important risk factor associated with recurrent chlamydia infection in women is failure of partner treatment (2, 3). Research has also demonstrated that providing medication to male partners of infected women can reduce rates of reinfection among the women. A recent multi-site randomized controlled trial of patient-delivered therapy funded by the Centers for Disease Control and Prevention demonstrated that patient-

delivered therapy reduced reinfection by 20%, from 15% to 12% (4). Although not formally evaluated in the trial, patient-delivered therapy should result in reducing infertility as well as healthcare costs associated with treating PID and infertility.

Adverse reactions beyond mild to moderate gastrointestinal distress to single-dose azithromycin are extremely rare. Unlike penicillins, macrolides are a class of antibiotics with very few allergic reactions. In the extremely unlikely event of an allergic reaction, appropriate therapy should be instituted.

### **New Options For Treating Partners**

As of January 1, 2001, California medical providers have a new option for ensuring partner treatment for patients with chlamydia. SB 648 (Ortiz, Chapter 835) amended current law and allows physicians to prescribe and nurse-practitioners, physician assistants and certified nurse-midwives to dispense antibiotic therapy for the male and female sex partners of individuals infected with genital *Chlamydia trachomatis*, even if they have not been able to perform an exam of the patient's partner(s). This new law provides an important means to combat a serious public health problem and prevent adverse reproductive health complications in women.

This option for the delivery of therapy for chlamydia is not intended as the first and optimal choice of treatment for partners of individuals diagnosed with chlamydia. But this therapy delivery system can serve as a useful alternative when the partner is unlikely to seek care or cannot easily get a timely evaluation or diagnosis. Providers should use their best judgment to determine whether partners will or will not come in for treatment, and decide whether or not to dispense to the index patient while available.

### **Current Health Care Provider Responsibilities**

Patients diagnosed with chlamydia infection cannot be considered adequately treated until all their recent partners have been treated. All sexual contacts within the past 60 days from the onset of symptoms or diagnostic test results need to be treated.

In California, physicians are still required by law to: 1) endeavor to discover the source of infection, as well as any sexual or other intimate contacts that the patient made while in the communicable stage of the disease (Title 17, California Code of Regulations, § 2636), 2) make an effort, through the cooperation of the patient, to bring these persons in for examination and, if necessary, treatment (Title 17, California Code of Regulations, § 2636), and 3) report cases to the local health officer (Title 17, California Code of Regulations § 2500).

## Guidance For Patient Delivered Therapy

Clinicians should make every effort to bring partners in for comprehensive healthcare including evaluation, testing and treatment. Clinical services provide the opportunity to confirm the diagnosis, examine the patient, test for other sexually transmitted diseases and pregnancy, and provide risk reduction counseling. These services are the standard of care for all partners of patients infected with a sexually transmitted disease.

The legislation permits patient-delivered therapy for both female and male partners of both female and male patients. Patients most appropriate for patient-delivered therapy are females with laboratory-confirmed genital chlamydia infection who are not co-infected with gonorrhea nor have any other complications. Most appropriate partners are males who are uninsured or unlikely to seek medical services. Because female partners may have pelvic inflammatory disease or another serious complication of chlamydia infection, or be pregnant, providers should make every effort to assist male patients in ensuring that their female partners get evaluated clinically and treated as necessary.

The legislation does not mandate a specific antibiotic. The recommended medication for patient-delivered therapy is single-dose azithromycin tablets (1 gram orally once) (5). While somewhat more expensive than the azithromycin powder (sachet) formulation, tablets are easier to deliver and facilitate compliance. Although doxycycline is an effective treatment for chlamydia infection, it requires dosing twice daily for seven days. Patients may be provided with the number of doses necessary to treat each of their known exposed partners with whom they've had sexual relations in the last sixty days; the law does not specify how many partners may be treated through this strategy.

The medication may be prescribed in one of three ways. The preferable method is to give a separate prescription for the patient and the patient's partner(s). It is also acceptable to include the name of the patient and partner(s) on one prescription. In the event the patient will not or can not name the partner(s), the provider may write a prescription for the patient "and partner(s) as appropriate," with the corresponding number of doses.

Ideally the medications and educational material should be given to the patient to deliver to the partner. If a prescription is used, then the provider should give both the educational material and the prescription, and encourage the patient to deliver both the medication and accompanying educational material to the partner. See Appendix A for an example of partner therapy instructions and information.

Providers should address three key counseling messages when prescribing patient-delivered therapy:

- Patients and partners should **abstain from sex for at least seven days** after treatment and until seven days after all partners have been treated, in order to decrease the risk of reinfecting the index patient.
- Partners should seek a complete STD evaluation as soon as possible.
- Partners who have allergies to erythromycin, azithromycin or other similar macrolides, have kidney failure, liver disease, heart disease, or any other serious

health problems, should not take the medication and should see a healthcare provider. If partners are unsure about any possible medication allergies or other health problems, they should consult a healthcare provider.

To ensure the effectiveness of patient delivered therapy, providers should schedule the patient to return for re-testing chlamydia three to four months after treatment.

**Please report any adverse reactions to the California Department of Health Services STD Control Branch to (866) 556-3730 (toll-free).**

---

\*Use of trade names is for identification only and does not imply endorsement

1. California Department of Health Services Sexually Transmitted Disease Control Branch. Sexually Transmitted Disease in California, 1998. Sacramento, 2000.
2. Whittington WL, Kent C, Kissinger P, et al. Determinants of persistent and recurrent Chlamydia trachomatis infection in young women: results of a multicenter cohort study. Sex Transm Dis **2001**; 28(2): 117-23.
3. Blythe MJ, Katz BP, Batteiger BE, Ganser JA, Jones RB. Recurrent genitourinary chlamydial infections in sexually active female adolescents. J Pediatr **1992**; 121(3): 487-93.
4. Schillinger J, Kissinger P, Berman S, Marin D, Calvet H. A Randomized Trial of Patient-Delivered Therapy to Prevent Recurrent Chlamydial Infection Among Adolescent and Young WOMen. National STD Prevention Conference. Milwaukee, 2000.
5. Centers for Disease Control and Prevention. 1998 Guidelines for Treatment of Sexually Transmitted Diseases. MMWR 47(RR1).

([http://www.cdc.gov/nchstp/dstd/1998\\_STD\\_Guidlines/1998\\_guidelines\\_for\\_the\\_treatment.htm](http://www.cdc.gov/nchstp/dstd/1998_STD_Guidlines/1998_guidelines_for_the_treatment.htm))

**URGENT and PRIVATE**  
**IMPORTANT INFORMATION ABOUT YOUR HEALTH**

**DIRECTIONS FOR SEX PARTNERS FOR TAKING  
AZITHROMYCIN**

PLEASE READ THIS VERY CAREFULLY

Your sex partner has recently been treated for *Chlamydia*. *Chlamydia* is a curable bacterial infection you can get from having sex with a person who already has it. Many people with *Chlamydia* do not know they have it because they have no symptoms and feel fine. Others may develop pain in their pelvis or testicles, when urinating, or during sex.

However, if you do not take medicine to cure it, you can get very sick. If you have unprotected sex with your partner, you could also reinfect them. Women can become unable to have children if they don't get treated.

You could have *Chlamydia*. It is important that you get treated. We want to be sure that you get the medicine you need as soon as possible. The best way to take care of yourself is to see a doctor or come to:

Telephone:

for a check-up and medicine. If you are not able to see a doctor within 1 week, you should take the medicine enclosed or prescribed as soon as possible.

**Before you take the medicine, please read the following:**

The medicine is very safe. However, **DO NOT TAKE** if any of the **following are true:**

- ◆ You are female and having lower belly pain, pain during sex, vomiting, or fever.
- ◆ You are pregnant.

Please turn over

- ◆ You are male and having pain or swelling in the testicles (balls) or fever.
- ◆ You ever had a bad reaction, rash, or allergy to the following antibiotics: Azithromycin (“Zithromax”), Erythromycin, Clarithromycin (“Biaxin”).
- ◆ You have a serious long-term illness like kidney, heart or liver disease.
- ◆ You are currently taking another prescription medication.

If any of these circumstances exist, you should talk to your healthcare provider as soon as possible.

**Some people get a mild upset stomach or diarrhea after taking this medicine. Others may develop dizziness, fatigue, or headache; a vaginal yeast infection; a rash; or become more sensitive to sunlight. These won’t last long. If you experience any other side effects or an allergic reaction, call your healthcare provider immediately. There can be other, more serious side effects, but these are extremely rare.**

***Don’t share or give this medicine to anyone else.***

Do not have sex for the next 7 days. It takes 7 days for the medicine to cure *Chlamydia*. If you have unprotected sex during the 7 days after taking the medicine, you could still pass the infection to your sex partners. While condoms are effective, the safest way to make sure you don't pass the infection on to anyone is to not have sex for 7 days.

If you have any questions about the medicine or *Chlamydia*, please call:

All calls are confidential. **No one will ask for your name.**

For a free STD exam, testing, and medicine, you can also come to:

## **Urgente y confidencial**

### **Indicaciones para la pareja sexual**

Por favor, lea esto con atención

Indicaciones para tomar el medicamento contra la CLAMIDIA (Azithromycin, 1 gramo)

Su pareja sexual ha sido tratada recientemente de Clamidia. Clamidia es una infección curable que se contrae por haber tenido relaciones sexuales con una persona infectada. Muchas personas con Clamidia no saben que tienen la infección, porque se encuentran bien. A pesar de ello, si usted no toma el medicamento para curarse, puede ponerse más enfermo y sentir dolor en la pelvis o los testículos, al orinar o durante relaciones sexuales. Si practica el sexo sin protección podría incluso infectar a su pareja de nuevo.

Es posible que Ud. tenga una infección de Clamidia. Es importante que haga el tratamiento y tome los medicamentos necesarios lo antes posible. La mejor manera de tratarse es visitar al médico o venir a:

Teléfono:

para un chequeo médico i obtener el medicamento. Si usted no puede acudir al médico antes de una semana, tome este medicamento lo antes posible.

Antes de tomar este medicamento, lea con atención las siguientes instrucciones:

Este medicamento es muy seguro. Sin embargo, NO LO TOME SI:

Es mujer y siente dolor de estómago o al mantener relaciones sexuales, tiene vómitos o fiebre;

Está embarazada;

Es hombre y siente dolor en los testículos o tiene fiebre;

Si ha tenido alguna vez reacción a algún medicamento o es usted alérgico a Azithromycin ("Zithromax"), Erythromycin, Clarithromycin ("Biaxin");

Tiene alguna enfermedad crónica de los riñones, el corazón o el hígado;

Está siendo tratado con otros medicamentos.

Si se da cualquiera de estas circunstancias, consulte su médico antes de tomar este medicamento.

Algunas personas pueden tener náuseas o diarrea después de ingerir este medicamento. Otras pueden experimentar vértigos, fatiga, o dolor de cabeza, infección vaginal leve, erupciones cutáneas o hipersensibilidad a la luz del sol. Estos síntomas no duran mucho tiempo. Si usted experimenta cualquiera de estas reacciones o una reacción alérgica, llame al médico inmediatamente. Raramente se producen efectos secundarios de mayor importancia.



No comparta ni proporcione este medicamento a ninguna otra persona.

Absténgase de relaciones sexuales durante los próximos siete días, porque son necesarios siete días para que este medicamento surta efecto. Si tiene relaciones sexuales sin protección durante los próximos siete días, puede infectar a su pareja.

Si tiene cualquier pregunta sobre este medicamento o sobre la Clamidia, por favor llame a:

Se le atenderá con la máxima confidencialidad.

Para un chequeo de otras enfermedades de transmisión sexual o la obtención de medicamentos también puede ir a:

06/13/01